



MedizinTechnik

English

Service instructions

ATMOS S 042 NPWT



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These service instructions mirror the technical conditions of the devices at the time when these instructions were written. Therefore, it is possible that figures in these instructions may deviate from the current product supplied.



1.1 Valid operating instructions

The operating instructions for the ATMOS S 042 NPWT form a part of these service instructions. Knowledge of their content, the method of setting up the device and commissioning it, as described therein, as well as how to handle the device, are essential for carrying out the service work.

1.2 Information of the manufacturer

Further information, accessories and spare parts can be obtained from:

ATMOS

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Deutschland

Tel. + 49 7653 689-0
Fax: + 49 7653 689-190
+ 49 7653 689-292 (Service Center)

atmos@atmosmed.de
www.atmosmed.de

1.3 Exclusion from liability

The manufacturer is not responsible for claims which can arise from repairs or service work, if these were not carried out by authorised people or were done by using others than the original spare parts of the manufacturer.

1.4 For your safety

If improper servicing or repair work is done on the device or non-original manufacturer's parts have been used the manufacturer ceases any product liability. If the device is opened during the warranty period the manufacturer's warranty becomes invalid.

In addition, please see Chapter 2.0 „For your safety“ in the operating instructions.

The servicing or the opening and the repair of the ATMOS S 042 NPWT must only be executed by an expert authorised by the manufacturer. When the work is being done technical and hygienic precautions shall be observed.



Before opening the device to carry out any service work the ATMOS S 042 NPWT must be switched off and the mains cable removed.

When assembling the housing special care should be taken with the electric cables. They must not be kinked or crushed.

If the servicing or repair of the device is not carried out properly or non-original parts are used the manufacturer's product liability expires. If the device is opened during the warranty period the manufacturer's warranty expires. If the device is scrapped at the end of its useful life and is to be disposed of, the components must be separated and put into the different recycling procedures. The same instruction applies to parts which have been replaced.

Device and accessories must be decontaminated prior to disposal as contaminated secretion residuals might be dangerous to health.



Hygiene measures during repair work

- Depending on the previous application the suction system and the waste water drainage system may be highly contaminated.
- For all works performed at the suction system or the waste water drainage system, gloves must be worn.
- The single-use gloves must be changed prior to touch other things respectively parts which are not contaminated.
- It must strictly be observed that no liquid or other residues escape from the suction system respectively the exhaust system. The contact of liquid and other residues from the suction system with skin, other things or persons must be avoided.
- Any leaked fluids from the suction system must immediately be removed with a cloth and a disinfectant cleaning solution. Afterwards thoroughly wipe the area with a suitable surface disinfectant. Please observe the contact time prescribed by the manufacturer!!
- The contact of liquid and other residues from the suction respectively the exhaust system with skin or clothes must be avoided.
- During work it is most important not to hurt yourself - **DANGER OF INFECTION!**
- Dismantled, contaminated parts which were replaced require waterproof and airtight packing and must then be disposed of professionally.
- After you finished your work you must thoroughly clean and disinfect the tools used. Please observe the contact time prescribed by the manufacturer!
- Furthermore please thoroughly clean and disinfect the working area with surface disinfectant. Please observe the contact time prescribed by the manufacturer!
- At the end you must thoroughly clean and disinfect your hands.
- For service technicians we recommend all required active immunisations.

Regular maintenance work at parts, which come into contact with patients and suction material, are performed by the user according to the descriptions in the operating instructions (annual calibration).



For safety reasons the device may no longer be operated in case it is oversucked.



In case a device was oversucked a repair makes no sense because the magnetic valves on the operating panel are soiled and contaminated. The secretion which penetrated the interior through the sound absorber is difficult to remove and the components may be damaged during cleaning.

3.0 Set-up and installation



Please read chapter 3.0 in the operating instructions

3.1 Ambient conditions



Transport/storage: -20...+50 °C; 5..95 % humidity without condensation at an air pressure of 700...1060 hPa

Operation: +5...+35 °C; 20...80 % humidity at an air pressure of 700...1060 hPa

Operating voltage: 100 – 240 V AC 50/60 Hz



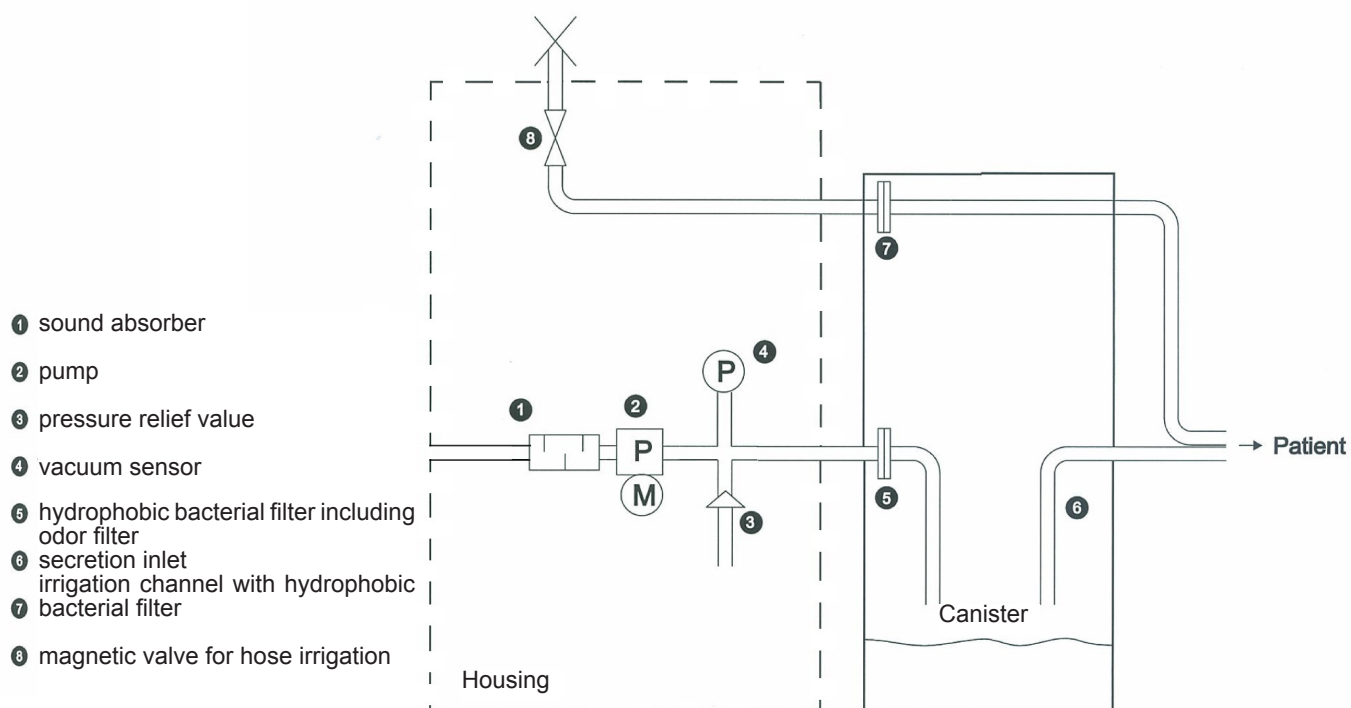
4.1 Set-up

The device is made of 2 plastic casings. It contains the main circuit board with a processor, recharge electronics with 12 DC power jack, pressure sensor, air relief valve, 2 USB connections, and on/off switch with LED. There is a touchscreen display installed between the casing and the main circuit board. The printed circuit board and the display are mounted by a plastic structure inside the casing. There is also a pump and a lithium ion battery, these are attached via a plastic clip. The tubing consists of silencers, vacuum overpressure valve (285 mmHg) and a small Piezo loudspeaker. On the rear side a snap-on interlock is used to mount the disposable plastic container.

4.2 Function

The easy to handle ATMOS S 042 NPWT is a suction device for the negative pressure therapy. The negative pressure device is operated with an electromotive, maintenance-free diaphragm pump. During operation the pump builds up negative pressure in the wound dressing, hose system and in the secretion container, this results in secretion evacuation. The negative pressure device produces, regulates and automatically monitors the preset therapy values. The secretion is collected in the provided secretion container. A special filter technology prevents the penetration of liquids, bacteria and odours into the interior of the device. Settings for the therapy can be conducted by means of a capacitive touchscreen. The negative pressure device is equipped with a lithium ion battery. It contains a microprocessor controlled recharging electronics which guarantee the safe charging of the battery. Due to the overcurrent protection, an overcharge of the battery is impossible.

4.3 Hose plan



4.4 Block diagram

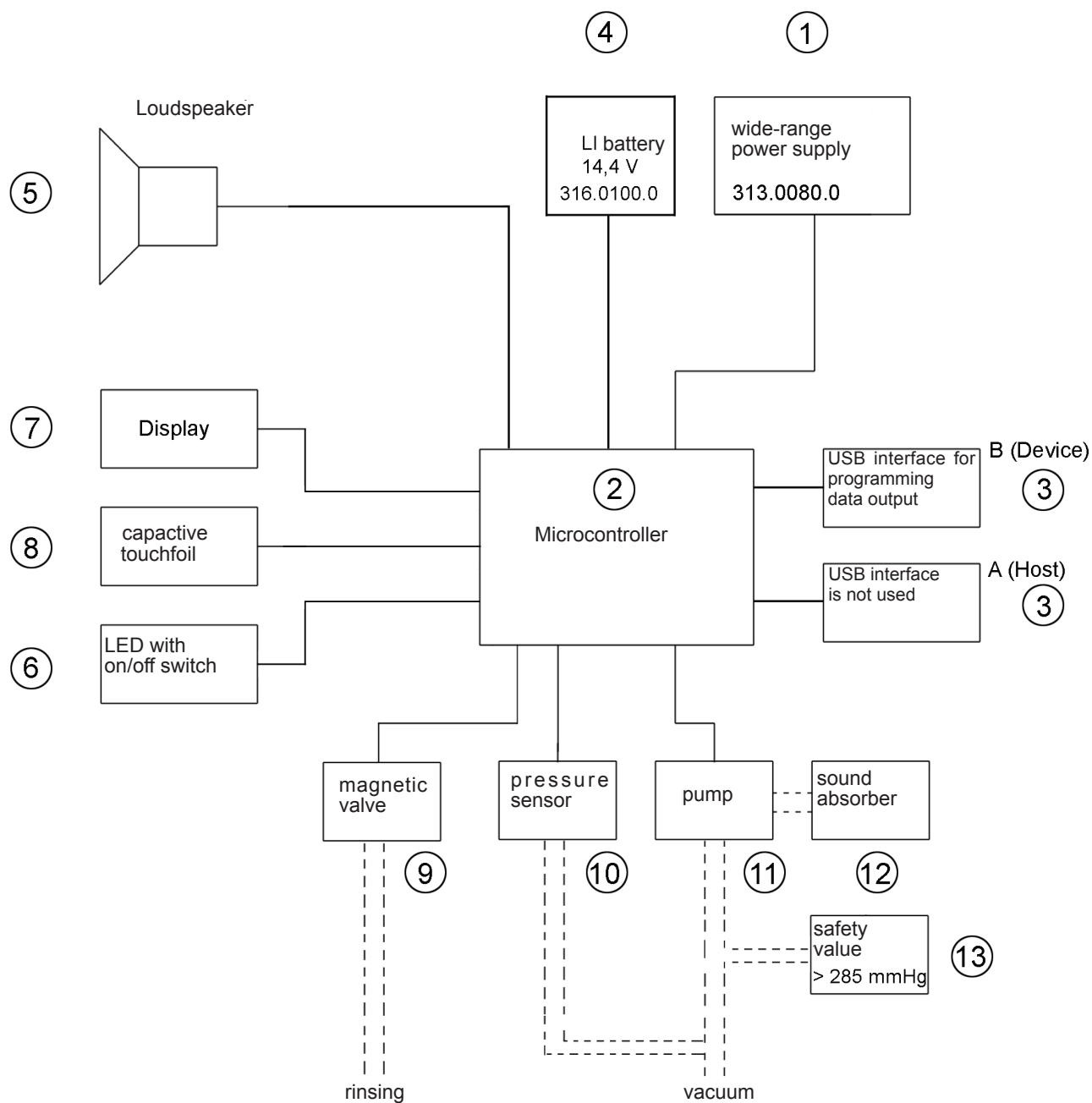


Fig. 1 Block diagram

4.5 Assembly description

1. Power supply

In a combinational circuit +12V direct voltage is generated. This voltage supplies the main circuit board, the pump and recharges the battery. The combinational circuit can be run with a supply voltage of 100-240 v 50/60.

2. Microcontroller

There is a microcontroller on the main circuit board for control of all functions.

3. USB-interface

There are 2 USB connections on the main circuit board which are accessible from the rear side. The square one (B) is used to play program updates and to transfer the therapy data to your PC via the USB cable. The other USB connection (rectangular shape A) is not used.



4. Battery

The device has a lithium-ion battery with 3 cells. These are connected in series. Each cell has a nominal voltage of 3,6 V. These are charged by the recharge electronics on the main circuit board.

The necessary safety electronics for the li-ion batteries is integrated in the battery pack.

5. Loudspeaker

For the acoustic reproduction of the alarm signal and the touch tone.

6. On/off switch with LED

The capacitive on/off switch is used to turn on/off the device. A green LED is activated when the device is in operating mode. The electric connection from the casing to the printed circuit board is guaranteed via an electric conductive spring.

7. Touch display

To indicate the setting values and menus.

For the operation of the suction device and the application of the menu.

8. Irrigation valve

The irrigation hose and the secretion hose are rinsed with air at regular intervals. The interval can be preset in the service menu between 3 and 20 minutes.

9. Pressure sensor

To measure the vacuum in the container system. The current measured values are only displayed in the service menu. On the display a circle with arrows, in different colours shows the impermeability of the system. Green signifies „system is leak-proof“ red signifies „system is leaky“. In between the two is also a yellow indicator.

10. Pump

Is operated with 12 V DC voltage. The speed is monitored by the control board via a tachometer and is registered by a PWM-signal.

11. Sound absorber

The air which is sucked in through the pump is then blown out into the environment via the sound absorber.

12. Safety valve

A mechanical safety valve prevents a high negative pressure. For instance, from a vacuum of 285 mmHg the valve opens and ensures pressure balance. After the valve is released it should then be exchanged.

5.0 Replacement of components



5.1 General information

Prior to use, conduct a visual inspection of the device as well as the mains adaptor and device connection cable.



Caution!

After exchanging the battery the exchange must be registered under „battery status“ (see chapter 7.7 battery-status).



Caution!

Having completed the service maintenance select the menu item „factory settings“ in the service menu. When the customer switches the device back on for the first time, the setting of the language will be automatically requested.



Caution!

The rectangular USB-port has no function!

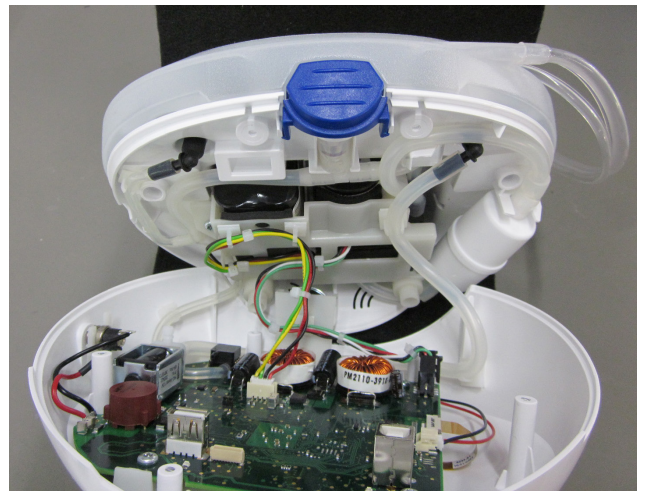
5.2 Disassembly and assembly of the device

Caution! Prior to opening the device switch off the device and remove the mains adapter!

5.3 Opening the device

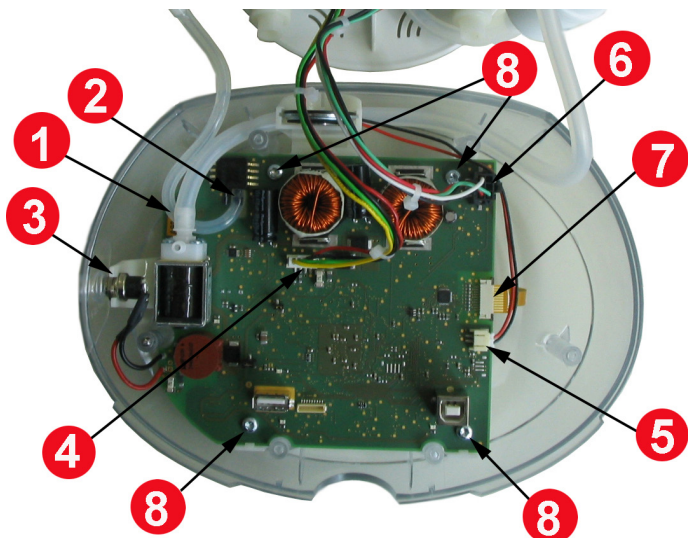


Loosen the 6 Torx screws on the rear side in order to open the device.



Gently unfold the front and back casing.

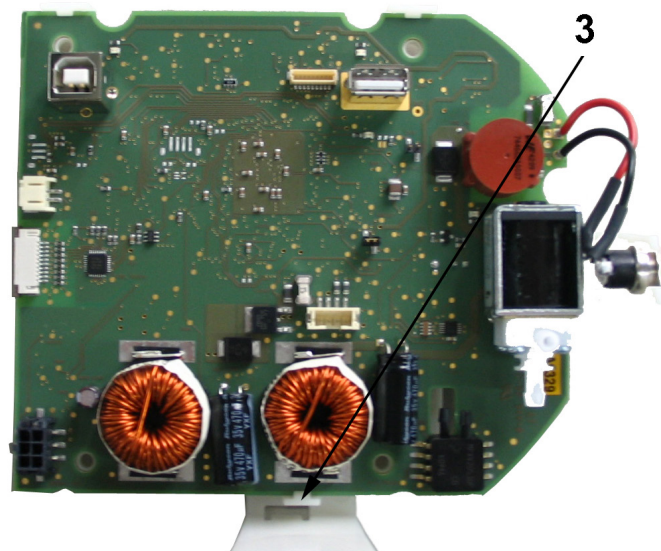
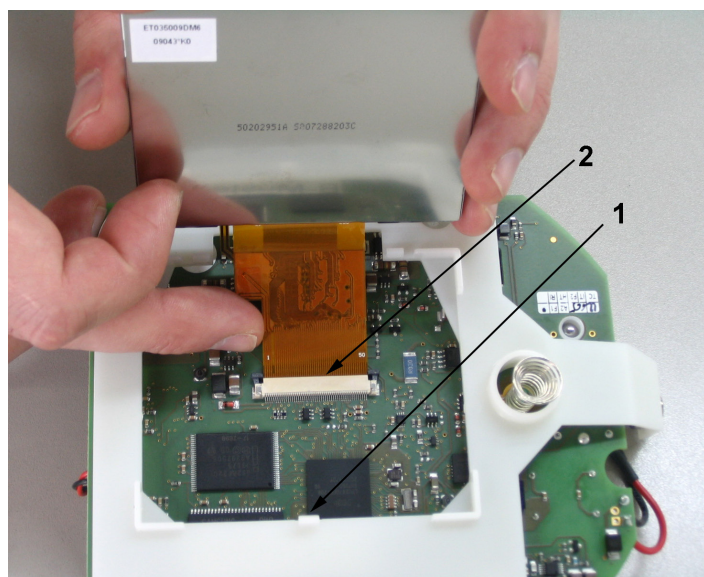
5.4 Disassembly of the printed circuit board and display



- ① Loosen the hose from the valve.
- ② Loosen the hose from the pressure sensor.
- ③ Gently loosen the screw nut of the charging socket and remove it from the support.
- ④ Unplug the battery.
- ⑤ Unplug the loudspeaker.
- ⑥ Unplug the plug from the pump
- ⑦ Gently unplug the connector from the keyboard
- ⑧ Loosen the 4 torx screws.

Now the complete unit, printed circuit board, support and display can be removed.

5.0 Replacement of components



- 1 Press the fastening clip forward and lift up the display.
- 2 Gently remove the ribbon cable from the connector. Now the display can be removed. Reassemble in the reversed order!
- 3 Remove the printed circuit board by pressing the clip.

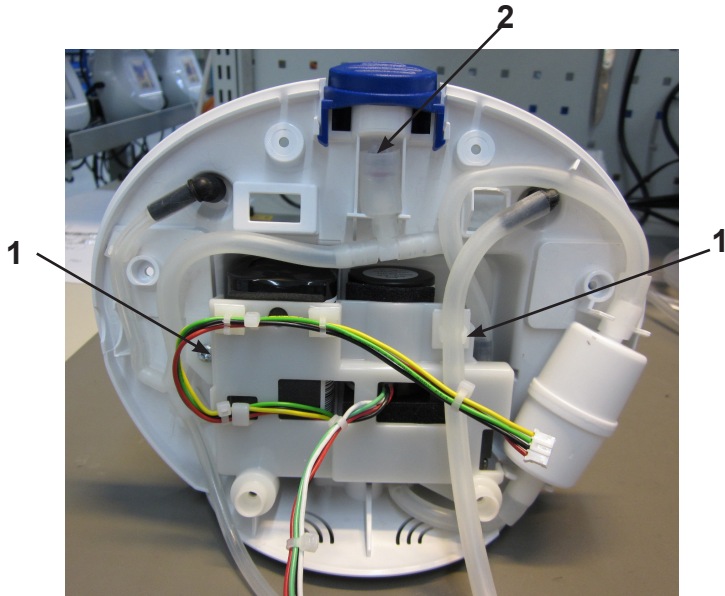
5.0 Replacement of components



5.5 To remove the battery and pump

First release the connector from the pump resp. from the battery on the printed circuit board. Loosen both screws 1, now both battery and pump can be removed.

Number 2 shows the safety valve which opens during an increased vacuum of more than 285 mmHg.



Caution!

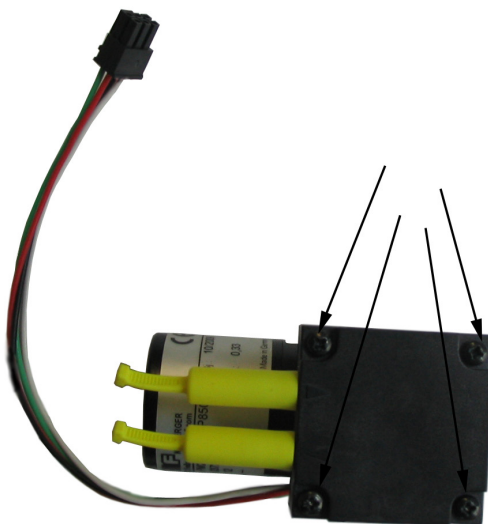
After exchanging the battery the exchange must be registered under „battery status“ (see chapter 7.7 battery-status). The battery should be exchanged every 24 months!



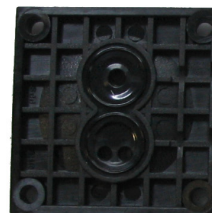
Caution!

Having completed the service maintenance, select the menu item „factory settings“ in the service menu. When the customer switches the device back on for the first time the language will be automatically asked.

5.6 Exchange of the pump components



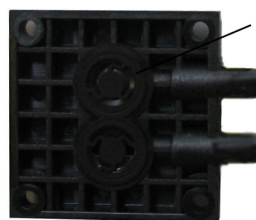
12 V Pump REF 000.0969.0



baffle plate



Membrane



valve plate

upper plate

Spare parts set for pump REF 069.0250.0

First loosen the 4 cross-head screws. Remove the pump cover, baffle plate and valve plate. Press the membrane with 2 fingers and unscrew. Reassemble in the reversed order!



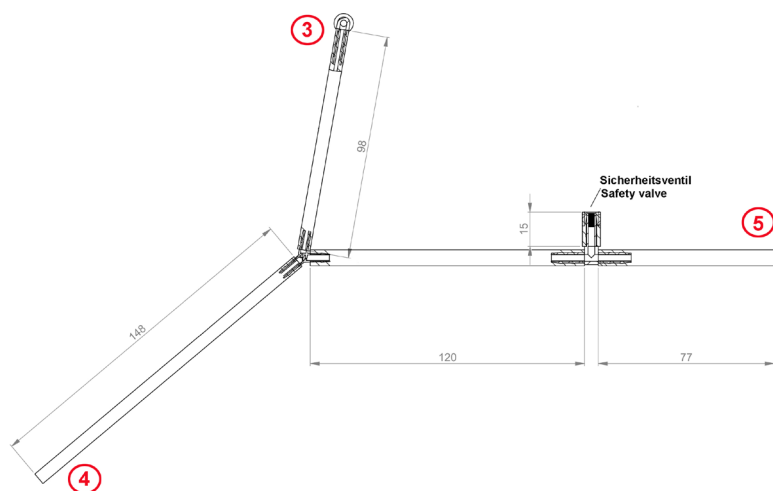
Caution!

If secretion enters into the pump all the components and complete hose harness must be exchanged during repair.

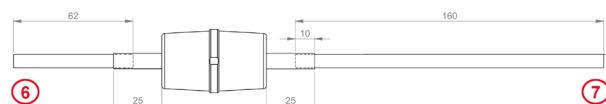
5.0 Replacement of components



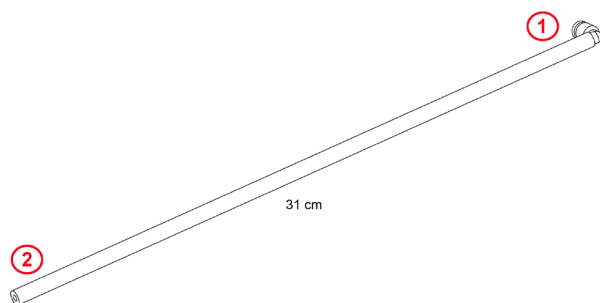
5.7 Mounting the hose system



316.0065.0 hose harness suction side

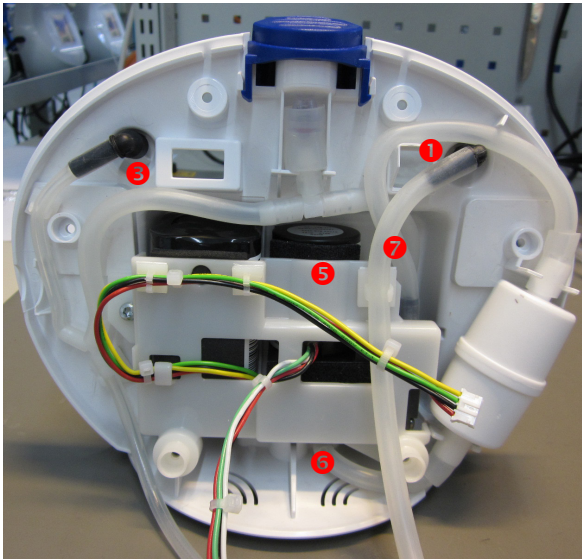


316.0066.0 hose harness for outlet side



316.0068.0 hose harness for irrigation side

5.0 Replacement of components



Adapt the hose harness of the outlet side from the pump discharge to the casing outlet.

The hoses must be attached accurately, as shown in the illustration. When putting the lower and upper part of the casing together, secure them over the dome



Caution!

Having completed the service maintenance, set „factory settings“ in the service menu.



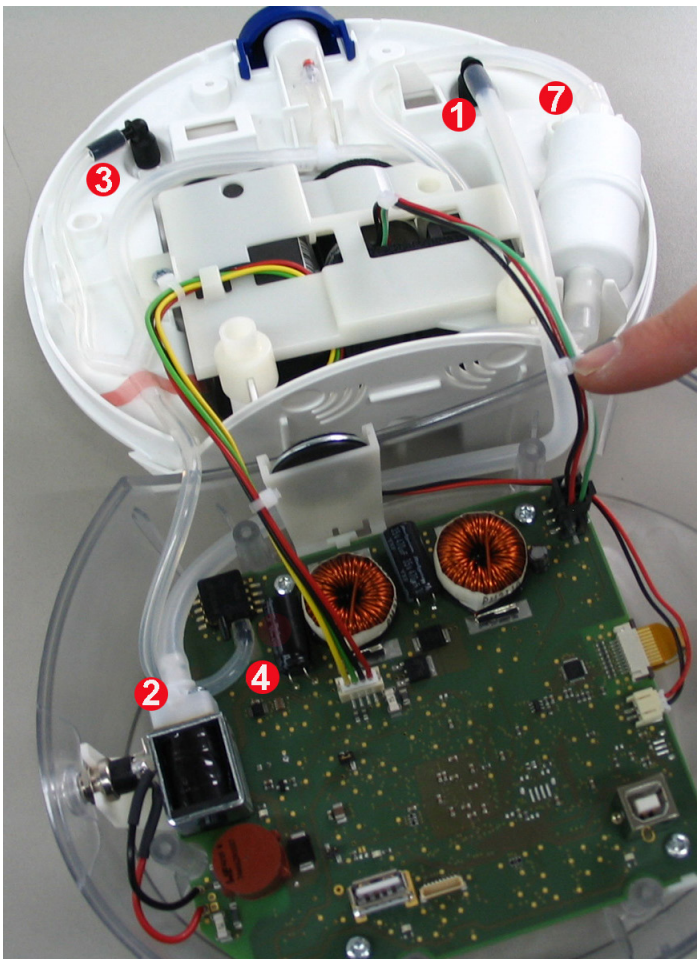
Caution!

The hose must not get caught when closing the casing.
Max. fastening torque 2,0 Nm



Caution!

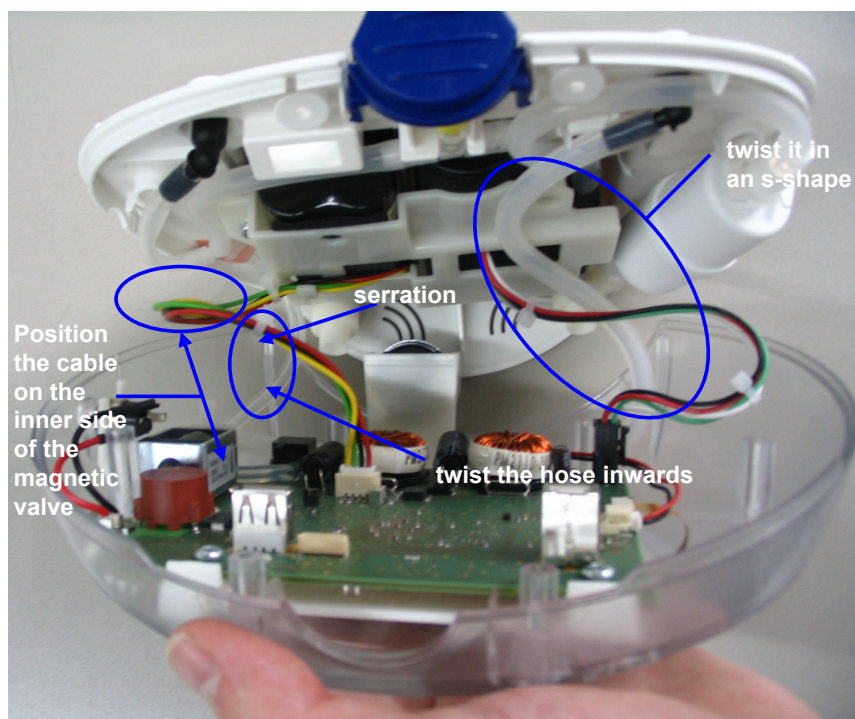
If the silicone hose must be removed from the control valve during repair, then it must be cut off directly at the valve. It should not be pulled off as this could result in damage to the valve.



5.0 Replacement of components



5.5 Putting the front and back casing together



Attention when joining the casing parts together, make sure the serration and the rear side of the casing is free. If you feel resistance in this area, please check.

1. Guide the two lower dome halves into one another.
2. Press the s-shaped hose to the side of the USB-input, with the help of an object (e.g. pen).
3. Slide both USB slots through the rear side of the casing, guide the remaining 4 screw spikes from both casing into one another.



5.0 Software Update

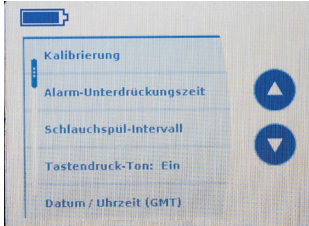


5.6 Software update

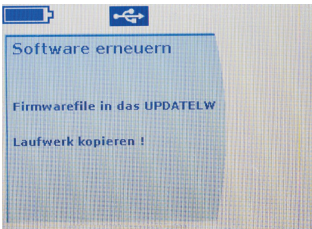


The device software can be updated via the USB interface.

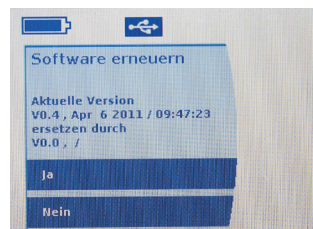
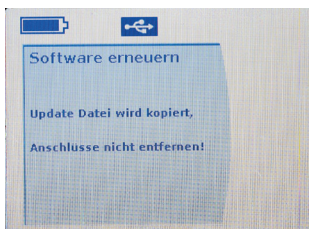
Click on service menu



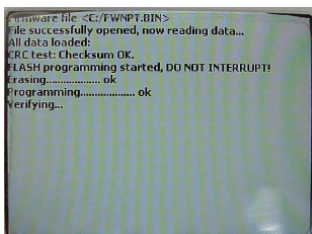
Remove the container and plug in the USB cable, it will automatically appear in the display:



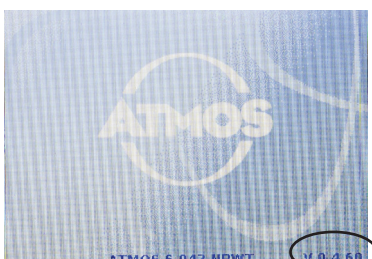
The drive „updateLW“ will automatically appear. Copy the update file into the drive „updateLW“



After the update the device will shut down automatically



Remove the USB flashdrive. Switch the device back on and check the software version in the service menu system.



6.0 Spare parts



316.0050.0	Front casing NPWT ATMOS	1 pc
999.2270.0	Rear casing	1 pc
316.0060.0	Printed circuit board NPWT ATMOS	1 pc
051.0321.0	Screw steel 3,5x10 LIN	4 pcs
000.0969.0	Pump membrane 5L/75%	1 pc
069.0250.0	Spare parts set for pump	1 pc
316.0056.0	Display and pump seal	1 pc
312.1011.0	Loudspeaker and cable	1 pc
316.0065.0	Hose harness, suction side	1 pc
313.0068.0	Hose RD.I. 4,0X2,0 with angle connection	1 pc
316.0066.0	Hose harness for outlet side	1 pc
316.0055.0	Support NPWT	1 pc
316.0100.0	Battery pack LI 451P	1 pc
316.0071.0	Bracket NPWT	1 pc
051.0321.0	Screw steel 3,5X10 LIN	2 pcs
316.0080.0	Key NPWT	1 pc
000.0968.0	Spring, pressure VD-117H-41	1 pc
999.2273.0	Strap fixation, left	1 pc
999.2272.0	Strap fixation, right	1 pc
051.0408.0	Screw Plastic Sts 3x16	6 pcs
442.0023.0	Self adhesive rubber feet 3.7937006	4 pcs
316.0090.0	Display for NPWT	1 pc
316.1110.0	Belt, attachment clip	2 pcs
316.1100.0	Shoulder belt	1 pc
313.0080.0	Battery charger MPV50A-3	1 pc
008.0866.0	Mains connection Zent.K-GER_BRG	1 pc
008.0006.0	Cable holder, miniature 6,1	1 pc
008.0007.0	Cable holder miniature 7,4	1 pc

7.1 Service menu access

The service menu can only be accessed when the device is switched off!

Switch off the device and then switch it on again. Keep pressing the button „on“

„ON“



As soon as the logo with the splash disappears press the button submenu.

„Submenu“



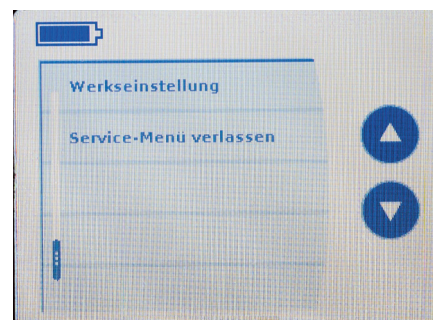
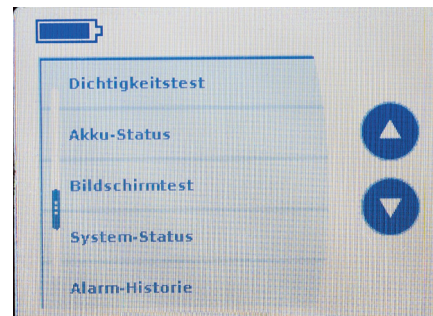
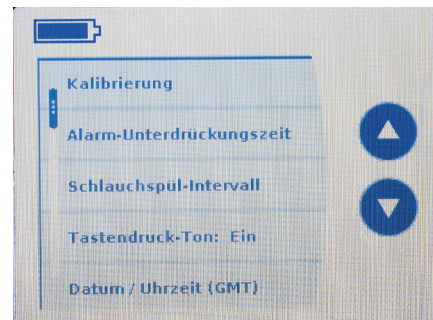
After the keytone resounds 3 times, the device switches into the service menu.

There are 12 submenus compiled in the service menu. The menus can be selected via the arrow keys. Click directly on the selected menu in order to enter the submenu.

The device must be switched off in order to exit the service menu. All amended values are saved!

If a function is not selected in the submenu for several seconds (approx. 20), the device switches back to the main menu without saving any values!

If a function is not selected in the main menu for several minutes (approx. 5) and the pump is not in operation the device shuts down completely.



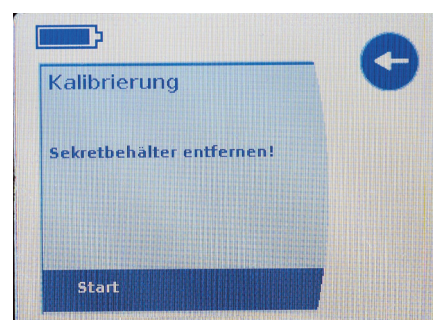
7.2 Service menu functions

7.2.1 Calibration

The device has a self-calibration. Please follow the instructions (remove the container and start the calibration).

The acknowledgement from the device is indicated via a green touchscreen with the reference „successful“ or a red touchscreen „unsuccessful“.

By a failed calibration the device calls for a service, level 2.



7.2.2 Alarm suppression time

Suppression time for error messages. Infinitely variable between 1 and 5 minutes.

Default: 3

7.2.3 Hose rinsing cycle

Interval when the hose is rinsed with air. Infinitely variable between 3 and 20 minutes.

Default: 5

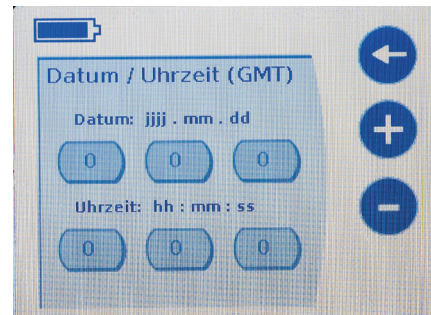
7.2.4 Keyboard sound

Default: on

7.2.5 Date/time (GMT)

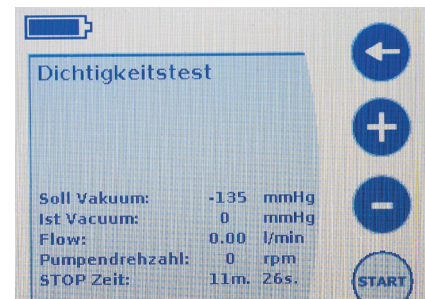
Adjustment of date and time.

The exact date and time is ex-works in GMT (Greenwich mean time, <http://www.greenmeantime.com>) or UTC (Coordinated Universal Time). Hence there is no conversion of winter to summer time. The date and time remain unaffected from the function factory settings.



7.2.6 Leakage test

To check whether the system is leak-proof (only the pump, not the consumables). At first the target value must be set according to the test protocol (200mmHg). Connect the hose end of the canister to the wound set.



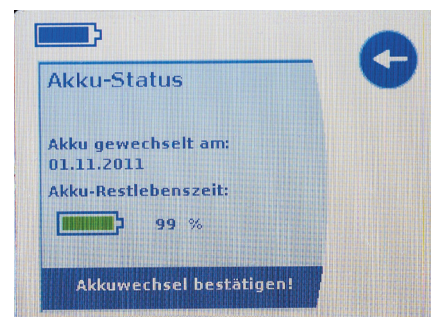
Press „start“ and wait until the current vacuum equals the target vacuum. Press „stop“ and monitor time and current vacuum. In 10 s the vacuum should not drop by more than 12mmhg. If the value is higher than 12mmhg within the 10 s the device requires a service, level 2.

7.2.7 Battery status

Indicates the state of charge and the remaining lifetime of the battery.

If the battery is older than 2 years or the remaining lifetime is under 30% then the battery must be replaced.

This calls for a service, level 2 and likewise for the function „confirm battery exchange“.



7.2.8 Display test

The device has an automatic display test. It is shown in black/white to identify pixel errors. In addition the display is shown in green, red and blue colours which helps to locate colour defects.

7.2.9 System status

In this menu device-specific data is stored:

Serial number
Software version
Hardware version
Operating hours
Date of the next safety test
The confirmation of the safety test is a service level 2 function.



7.2.10 Alarm history

Up to 50 errors are displayed in chronological order.

When the memory is full the oldest entry will be deleted.

In order to delete the complete error memory press:



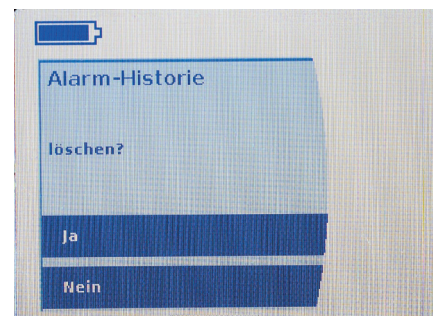
The error memory is also deleted if the function „factory settings“ is reset.



7.2.11 Factory settings

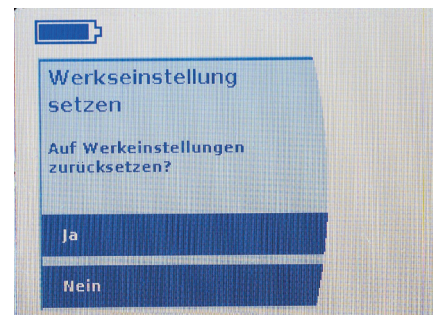
Via the function „reset factory settings“ the following values are reset to „Default“:

- All parameters from the basic settings (flow values from the mode continuous and flow and time values from the mode intermittent, brightness)
- Language choice (when the device is switched on)
- Alarm suppression time
- Hose rinsing cycle
- Keyboard sound
- Alarm history
- Data storage



7.2.12 Exit the service menu

Exit and storage of the service menu. The device shuts down and saves the settings.





8.1 Visual inspection of the housing, display

All mechanical parts must undergo a visual inspection regarding the correct attachment, flexible parts must be checked for mobility and support parts for damages. Attention must be paid to the following points:

Check the device for visible faults or damages (e.g. cabinet damage, screw connections etc.)

- Check the completeness and legibility of the inscriptions (especially the security-related inscriptions)
- Check the fuses and correct values according to the details on the name plate
- Check the device for signs of corrosion, damage and contamination.

8.2 Software version

When the device is switched on the current software version is briefly indicated on the display e.g. V 2.44.

8.3 Function check

Check the keyboard and container interlock, check the key lock. Connect the power supply. Check whether the battery is charging.

8.3 Measured values

The measurements are conducted with containers. Measure the maximum vacuum with the vacuum meter. The maximum litre capacity is measured with the flow meter.

8.4 Impermeability

Adjust the device to 200 mmHg and when the vacuum is achieved, switch it off. The vacuum should not fall by more than 12 mmHg within 10 seconds.

8.5 Control accuracy

Adjust the default value to 80 mmHg the measurement should only vary between ± 6 mmHg.

8.6 Power supply function

Check the power supply function. Check whether the battery is charging.

8.7 Clear error memory

Clear error memory in the service menu.

8.7 Check the date resp. adjust

The date must be adjusted in GMT-time. (time - 1 hour, resp. summer time - 2 hours)

8.8 Confirm battery exchange

A confirmation in the service menu is only necessary if the battery was exchanged.

8.9 Confirm STK

STK must be confirmed in the service menu.

8.10 Monitor screen test

In the service menu the colour fidelity and the pixels are tested. All the pixels are activated so that errors can be recognized. During the colour test all available colours are successively displayed.

8.11 Check factory settings

Adjust the vacuum value, adjust the intermit value 4 and the illumination. Set to factory settings, afterwards the device must be adjusted with the following values: illumination to 5, intermit 20 mmHg as well as every 3 minutes. Vacuum value to 125 mmHg.

8.0 Inspection specifications








Device	<input type="checkbox"/> ATMOS S 042 NPWT 316.0000.0 <input type="checkbox"/> VivanoTec NPWT 999.2200.0
Serial number:	
Classification according to EC Directive 93/42 EEC	Ila
Protection class (IEC601)	I
Degree of protection	IP 33
Inspection acc. to	MPBetreibV §6 Abs. 1
Test standard	IEC 62353 / VDE 0751-1
Verification period	annually

Cleaning and surface disinfection performed	<input type="checkbox"/>
Battery charged, charging indicator 100 %	<input type="checkbox"/>
Visual inspection Cabinet and display have no cracks/damages. Connections and interfaces on the rear side without damage, harness attachment is available and without damage.	<input type="checkbox"/>
Inscription on the mains input is legible. Name plates exist and are clearly legible.	<input type="checkbox"/>
Mains adapter and mains cable without damages. Labelling clearly legible.	<input type="checkbox"/>
Testing in the user menu (switch on the device)	
Function check Plug in the power supply and check whether the battery is charging. Check the buttons on the touchscreen (on/off, start/stop and +/-) adjust to 200 mmHg for a later leak test.	<input type="checkbox"/>
To check the service menu (switch off the device, now switch it back on and press the button combination in order to access the service menu.)	
Select calibration Remove the container and press start.	<input type="checkbox"/>
Select date/time (GMT, http://wwp.greenwichmeantime.com/) Check and adjust if necessary.	<input type="checkbox"/>
Select impermeability Connect the sealed container (by 200 mmHg nominal value decrease in pressure under 12 mmHg in 10 seconds). Note the values according to 10s. Passed (value must be >197 mmHg)
Select battery status If the battery is older than 2 years or the remaining lifetime is under 30% then the battery must be replaced.	<input type="checkbox"/>
Select monitor test Black/white display without pixel errors. The primary colours are displayed without any colour errors.	<input type="checkbox"/>
Select system status Document the software version. The next safety test may only be conducted in 6 months time.	<input type="checkbox"/> SW:
Select factory settings Adjust to factory settings (condition on supply)	<input type="checkbox"/>
Device complementation (condition on supply) user manual, cabinet, shoulder strap, power cable	<input type="checkbox"/>
Device in order □□□□□□□□□□□□ Device not in order □□□□ _____ _____ <div style="display: flex; justify-content: space-around; margin-top: 10px;"> Inspector/stamp Date </div>	

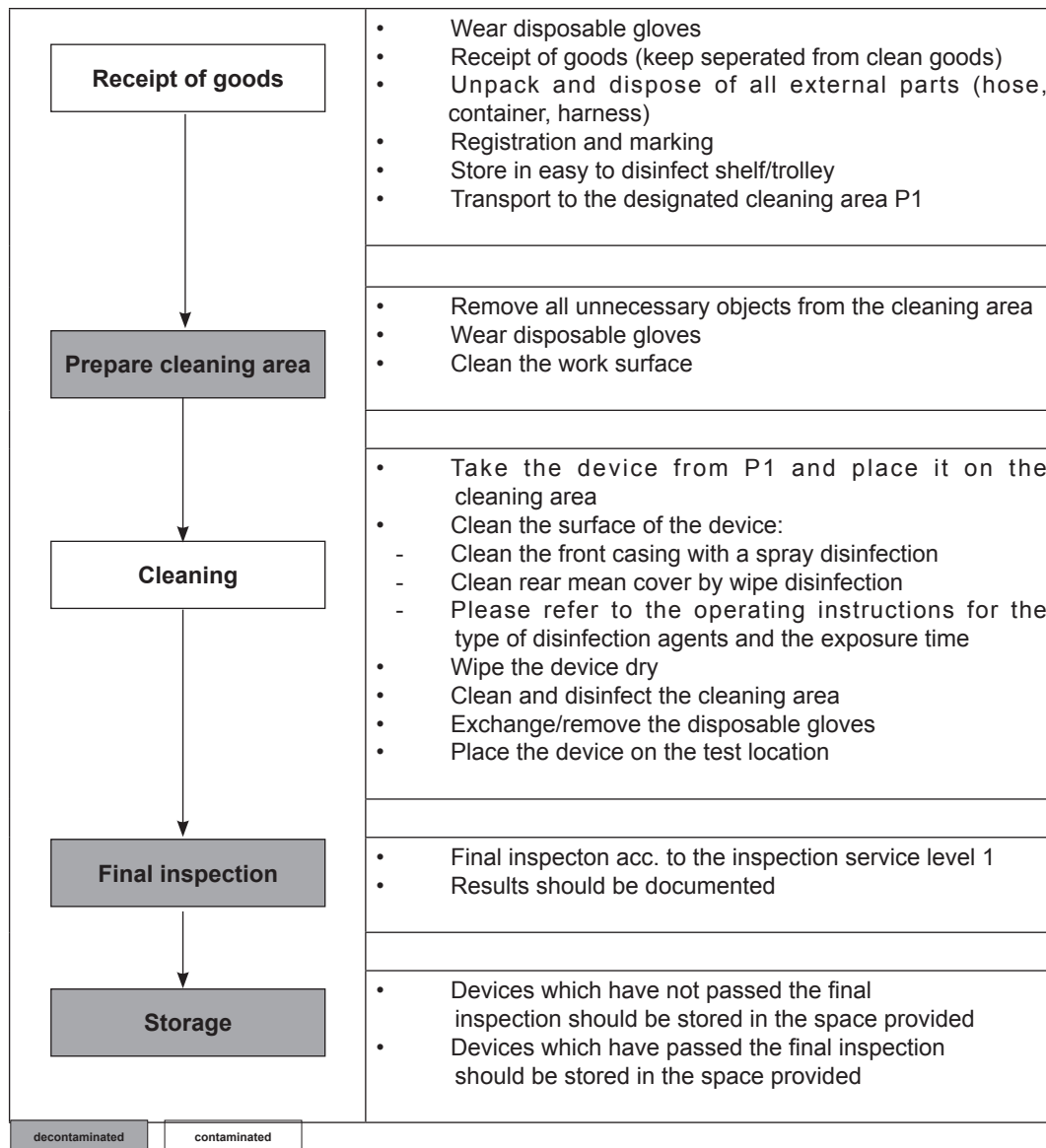


Batteries are consumables with a limited lifetime. After approx. 500 charging cycles the lithium-ionic-batteries are consumed and must be replaced. The handling of the device resp. the batteries has a decisive influence on the lifetime of the batteries. Depending on how they are stored, a battery can loose capacity, that is approx. 4% of the current charging by 25°C per year. The self-discharge is approx. 1% per month. Non-compliance with the following points can reduce the lifetime considerably.

-  **Batteries should be stored in a cool and dry place**
-  **Batteries should be charged to 30% prior to storage**
-  **To prevent deep discharge during storage, batteries should be charged to at least 30% every 6 months**
-  **The lifetime of lithium-ionic-batteries depends mainly on the ambient temperatures. After approx. 2.5 years the batteries are consumed.**
-  **New batteries must be fully charged prior to first use.**


A deep discharge can destroy lithium-ionic batteries (danger of explosion!)

ATMOS has absolutely no influence on the handling of the devices, therefore batteries are excluded from the general warranty. If an error occurs within 6 months after purchase a manufacturing defect may safely be assumed. Therefore ATMOS gives a function guarantee of 6 months on all batteries.



11.0 Technical data



Voltage	100- 240 V~, 50/60 Hz connector socket IEC320 Type 14
Power input	--
Power consumption	max. 60 VA
DC voltage	12 V DC +/- 2 %, max. 4 A via cable 1.8 m long with plug 5.5 x 2.5 mm alternatively via automobile cable from the cigarette lighter charger
Battery, integrated	Li-Ion, 14.4 V nominal, 2250 mAh charging time max. 2 hours at room temperature, Automatic switching to trickle charge
Operating time	operation up to 16 hrs. at 80 mmHg und 0,4 l/min Leakage Capacity indicator in the display during operation and charging Continuous operation with the mains power supply
Pump	membrane pump, 1 pump head
Flow	max 4,5 l/min freeflow (without filter, damper and hose)
Vacuum	Max. 500 mmHg (pump performance at sea level), yet mechanical and due to the electronic control, restricted
Vacuum control	electronically controlled, max. 250 mmHg, min 20 mmHg in steps of 5 mmHg, a connected container is required for a stable vacuum
Display	graphic display, colour with backlighting, ambient light adaption and automatic switch off (power save mode)
Operation modes	Continuous suction or intermit/selectable
Battery recharging and pumping are possible at the same time	
Data storage	internal storage for therapy data: 4MB corresponds to 4 years recording
Earth leakage current	max. 0,5 mA
Ambient conditions	
Transport/Storage	-20...+50 °C 5...95 % humidity without condensation at an air pressure of 700...1060 hPa
Ambient conditions	
Operation	+5...+35 °C 20...80 % humidity without condensation at an air pressure of 700...1060 hPa
Dimensions HxBxD	164 x 206 x 95 mm without container Depth with 300 ml: max. 115 mm Depth with 800 ml: max. 128 mm
Weight:	1.7 kg without container, with power supply and cable 1.9 kg with empty container 300 ml 2.0 kg with empty container 800 ml
Recurring safety tests according to the regulations for the prevention of industrial accidents, should be performed every 2 years. ATMOS recommends an annual safety test and maintenance acc. to the information in the operating instructions	
Protection class (EN 60601-1)	I, earth conductor, only for EMC
Applied part	type BF 
Degree of Protection	IP 33
Classification acc. to appendix IX	Ila
EC Directive 93/42/EEC	
CE-labelling	CE 0124
Applied standards	see list in the product master file, chapter 4
UMDNS-Code	Suction Unit Wound 10-223
GMDN-Code	Aspirator, Wound 10223

ATMOS General terms and conditions

1. General:

Our General Standard Terms and Conditions apply exclusively. Client's terms and conditions which are contrary to or deviate from our General Standard Terms and Conditions are not recognised unless their validity is explicitly confirmed in writing. Our General Standard Terms and Conditions also apply even if we deliver to clients without reservation, in the knowledge of the client's contrary terms and conditions. Our General Standard Terms and Conditions also apply to all future business with that client.

2. Proposal - Order Confirmation

Our proposals are subject to change without notice unless otherwise stated in our order confirmation. Each order is only accepted by us following our written order confirmation.

3. Orders

Every order requires an exact description of all of our product's details. We assume no liability for errors and damage caused by inaccurate or incomplete ordering details.

4. Prices

Unless otherwise stated in the order confirmation, our prices in the order confirmation are ex factory prices and exclude packaging and value added tax. Packaging is charged separately at cost price in the invoice. Value added tax is charged separately in the invoice according to the legal rate on the invoice date. We reserve the right to change prices appropriately should price reductions or increases, especially due to wage settlements, changes in the price of materials or currency fluctuations, be incurred. Proof of such changes will be provided for the client on request.

5. Payment Conditions - Balancing

Unless otherwise stated in the order confirmation, our invoices are payable with a 3% discount within 10 days (except for repair and assembly services) or within 21 days from the invoice date net cash; money receipts is decisive for complying with this term. We are entitled to charge interest after the due date at a rate 2% above the relevant basic interest rate of the German Federal Bank. Should the client have payment arrears, we are entitled to charge interest on arrears at a rate 5% above the relevant basic interest rate of the German Federal Bank. Should we be able to prove higher damages due to arrears, we are also entitled to claim these. The client only has the right to balance invoices against its own claims should such claims be confirmed in a court of law or recognised by us. The client does not have the right of retention due to disputed counterclaims.

6. Delivery Periods

Fulfilment of our delivery duties requires the punctual and proper fulfilment of the client's duties. The right to defense on the grounds of an unfulfilled contract is reserved. Should the client default in accepting the goods delivery or breach other cooperation duties, we are entitled either to withdraw from the contract or claim compensation for any increased costs incurred up to that time without setting a further deadline. The right to make further claims is reserved. Furthermore, in such cases, the risk of coincidental destruction or a coincidental deterioration in the quality of the delivered goods is transferred to the client in the case of default in accepting such goods or payment arrears. Acts of God or stoppages (due to insufficient supplies of material, industrial disputes etc.) entitle us either to demand an appropriate extension of delivery periods or to partly or entirely dissolve the delivery contract. This does not give the client the right to claim damages. We have fulfilled delivery periods if the delivery goods have left our factory or the client has been informed of the goods' readiness for delivery within such delivery periods. Delivery periods stipulated by the client are not recognised by us unless they form part of our order confirmation. We adhere to legal terms and conditions in cases where, as a result of an undue delay in the delivery for which we are liable, the client is entitled to claim that his interests in a continued fulfilment of the contract have ceased. We also adhere to legal terms and conditions should a delay in delivery be caused by deliberate or grossly negligent action by us or our representatives for which we are responsible. We are also responsible for such actions by our representatives or agents. Should the delivery delay not be caused by our deliberate infringement of contractual duties for which we are responsible, our liability is limited to damage which is regarded as typical for that case. We are liable according to the legal terms and conditions if and in so far as the delivery delay for which we are responsible is caused by an infringement of a substantial contractual duty. In such cases, our liability is also limited to damage which is regarded as typical for that

case. Should the delivery delay be caused by a culpable infringement of non-substantial contractual duties, our client is also entitled to claim a one-off damage compensation worth 3 percentage points of the delivery value of the goods for each week's delay, up to a maximum which is no higher than 15 percentage points of the delivery value of the goods

7. Delivery - Familiarisation

In the case of the delivery of devices for the medico-technical industry which require assembly and/or familiarisation for the final customer using specialist trade personnel (such as Ear, Nose and Throat Apparatus and Suction Units), we reserve the right to deliver the goods exclusively to the relevant specialist traders. Should the trader not carry out assembly and/or familiarisation for the final customer, this is carried out by us. In such cases, we reserve the right to charge the client for the additionally created costs. Our specialist traders operate a recording system so that, if necessary, our products can be traced to the final customer. The specialist trader undertakes to immediately report to us all events and risks which must be reported in connection with our products.

8. Passage of Risk - Packaging

Unless otherwise stated in our order confirmation, delivery is agreed ex factory. The risk of the goods' damage or loss is therefore transferred to the client as soon as the goods leave the factory or the client is in default of acceptance of the goods. This also applies to cases where we confirm prepaid carriage. Transport packaging and all other packaging according to the packaging regulations is not returnable. Our client is responsible for disposing the packaging at its own cost. Our deliveries are insured by us at the client's expense unless explicitly otherwise agreed. No insurance is arranged in the case of goods which are collected by our clients. In the case of transport damage, claims are only handled if the client receives confirmation of any damage, reduced weight or loss by the shipping company before accepting the delivery.

9. Warranty

The client is responsible for examining the delivered goods immediately after receiving them to determine any eventual deficiencies or delivery errors, and to report these immediately. Should the client fulfil this examining and reporting responsibility, and should payment conditions be fulfilled, we shall be liable to the client within the scope of legal regulations. Our period of warranty shall in all cases be two years. Our client can make use of the warranty as follows, so long as he can provide first buyer proof (in the form of an invoice or delivery note) and provided that the product still has the original, unchanged serial number:

- a. We choose whether to fulfil our guarantee by providing repair services free of charge - either on the client's premises or in our factory - or replacing the product. We can also provide these guarantee services through an authorised company;
- b. Should a product be returned to us, the client agrees to send the product in its original or similar packaging, offering the same protection as the original packaging, to our address or any address notified by us.
- c. Our guarantee ceases to apply if changes of any kind have been made to our product, unless such changes have been made by us or a company authorised by us, or have been previously agreed upon in writing by us. Our guarantee also ceases to apply if third parties have carried out repairs to our products or replaced parts thereof. This applies regardless of the fact whether these measures individually or collectively led to a deficiency of the product;
- d. We accept no responsibility for damage defects caused by
 - operational wear and tear;
 - incorrect installation or incorrect or insufficient maintenance;
 - incorrect operation of the product (in contradiction to the operating instructions delivered with the product);
 - improper use or operating faults;
 - inappropriate or negligent handling and care, especially with respect to dirt, lime, suction of fluids, inappropriate cleaning and sterilisation;
 - using accessories and/or replacement parts which are not explicitly approved;
 - incorrect assembly and/or initial operation by the client or third parties;
 - the client's negligence in handling the product;
 - unacceptable operating conditions, such as humidity, temperatures, the power supply, vibrations.
 - accidents, acts of God, especially lightning, water, fire, public unrest and insufficient ventilation. We are not liable for damage to other objects apart from our product itself, except in the case of any deliberate or grossly negligent actions by us or our representatives or agents. Should no deliberate breach of contract be claimed, our liability

is limited to damage which is regarded as typical for that case. This also applies in the case of our culpable infringement of substantial contractual duties. The indispensable conditions of German Liability Law remain unaffected thereby.

- For second-hand equipment, the period of warranty shall be reduced to a period of twelve months.

10. Reservation of Ownership

We retain ownership of our goods until the receipt of all payments arising from the business relationship, including all demands arising from installation orders, subsequent orders, repairs, accessory deliveries and replacement orders. Should we have agreed upon payment on the basis of cheque and bill transactions, the ownership reservation applies until the cheque received by us has been paid in, and does not expire through our credit upon receiving the client's cheque. In the case of a breach of contract by the client, especially payment arrears, we are entitled to repossess our goods. Repossession of our goods represents a withdrawal from the contract, unless explicitly declared in writing by us. We have the right to utilise the product after its repossession, whilst the income from such use is balanced against the client's arrears, after deducting appropriate utilisation costs. The client is responsible for handling the goods with care. Should maintenance and inspection work be necessary, the client must carry these out punctually at his own cost. Our client is entitled to sell the goods he has bought from us in a proper sale transaction. However, he must immediately assign all outstanding claims to the value of the final invoice sum (including value added tax) of our claims to his customers or third parties. The client is entitled to collect this claim even after such assignment. Our right to collect the claim ourselves remains unaffected thereby. We undertake to release the securities to which we are entitled if requested to do so by the client should the realisable value of the securities be more than 10 percentage points higher than the outstanding claims. We reserve the right to choose the securities to be released.

11. Plans and Illustrations

We retain ownership of and copyrights to all plans, illustrations, calculations and other documents which are attached to our proposals. The client must receive explicit written permission before passing these on to third parties. Imitating our legally patented products is forbidden and will be prosecuted.

12. Jurisdiction and Place of Performance

Our central office is the place of performance for all disputes in connection with these General Standard Terms and Conditions and the contracts closed with clients under them. This jurisdiction excludes other jurisdiction relating to persons or subject-matter. Furthermore, our client is not entitled to bring charges against us in another court should he file counter-charges, carry out counterbalancing or declare retention. We, however, are entitled to bring charges against our client at their general place of jurisdiction or at another relevant court recognised by German or foreign law. Unless otherwise stated in the order confirmation, our central office is the place of performance.

Lenzkirch, September 2008
ATMOS MedizinTechnik GmbH & Co. KG
79853 Lenzkirch/Germany

EG - KONFORMITÄTSERKLÄRUNG EC - DECLARATION OF CONFORMITY DECLARATION DE CONFORMITE CE

Wir / We / Nous ATMOS MedizinTechnik GmbH & Co. KG
Ludwig-Kegel-Straße 16
79853 Lenzkirch/Germany
Tel. +49 7653 689-0

erklären in alleiniger Verantwortung, dass das Medizinprodukt /
declare under our sole responsibility that the medical device /
déclarons sous notre pleine et entière responsabilité que le produit médical

Klassifizierung / Classification / Classification : II a

Name / name / Nom:  ATMOS S 042 NPWT

REF 316.0000.0

Varianten / models / Variante:

allen anwendbaren Anforderungen der Richtlinie 93/42/EWG entspricht. /
meets all applicable requirements of the Directive 93/42/EEC /
répond à toutes les exigences applicables de la directive 93/42/CEE

Name, Adresse und Kennnummer der Benannten Stelle:
Name, address and identification number of Notified Body:
Nom, Adresse et Numéro d'identification de l'organisme notifié :



DEKRA Certification GmbH, Handwerkstraße 15, D-70565 Stuttgart

Konformitätsbewertungsverfahren:	Richtlinie 93/42/EWG Anhang II des Rates über Medizinprodukte vom 14. Juni 1993, zuletzt geändert am 5. September 2007 /
Conformity assessment procedure:	Directive 93/42/EEC Annex II on medical products, passed by the commission on 14th June 1993, last amended on 5th September 2007 /
Procédé d'évaluation de conformité :	Directive 93/42/CEE, Annexe II du Conseil sur les produits médicaux, passée en commission le 14 juin 1993, dernière modification le 5 septembre 2007.

Gültig bis auf weitere Änderungen am Produkt bis 29. März 2015.
Valid till further changes on the product until March 29th 2015.
Valide jusqu'à modification du produit, jusqu'au 29 mars 2015.

Lenzkirch, den 04.06.2013
Place and date of issue


Frank Greiser
Geschäftsführer /
Managing Director / Directeur


i.V. Steffi Focke
Sicherheitsbeauftragter / Safety
Inspector / Chargée de la Sécurité